



Frequently Asked Questions About Generic Drugs

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1. What are generic drugs?

A generic drug is chemically the same as a brand-name drug in active ingredients, dosage, safety, strength, how it is taken and intended use.

(Source: FDA)

2. Are generic drugs as safe as brand-name drugs?

Yes. The U.S. Food and Drug Administration (FDA) requires that all drugs be safe and effective. Generics use the same active ingredients and are shown to work the same way in the body; so, they have the same risks and benefits as their brand-name counterparts.

(Source: FDA)

3. Are generic drugs as strong as brand-name drugs?

Yes. The FDA requires generic drugs to have the same quality, strength, purity and stability as brand-name drugs.

(Source: FDA)

4. How do doctors feel about generic drugs?

The American Medical Association, the largest organization of medical doctors, states that generic drug products are acceptable for use by the American public. Most hospitals routinely use generic drugs for treatment of their patients.

(Source: AMA)

5. Do generic drugs take longer to work in the body?

No. Generic drugs are made to work in the same way and in the same amount of time as brand-

name drugs.
(Source: FDA)

6. Why are generic drugs less expensive?

Generic drugs are less expensive (usually 30-75 percent less, according to the Generic Pharmaceutical Association) because generic manufacturers don't have high research and advertising costs. They can sell their product at substantial discounts. Once generic drugs receive FDA approval, there is greater competition, which keeps the price down. Today, almost half of all prescriptions are filled with generic drugs, according to the FDA.
(Source: FDA)

7. Why does it take so long for a generic drug to become available?

Manufacturers of brand-name drugs usually receive patent protection after spending the time and money to research and develop a drug. That protection prevents other companies from making and selling their own version of the drug until the patent expires, which may take up to 20 years. After a patent expires, other companies can create and market their own version of a brand-name drug (based on the process described in the patent) if they receive FDA approval.
(Source: FDA)

8. Are brand-name drugs manufactured in more modern facilities than generic drugs?

No. Both brand-name and generic drug facilities must meet the same standards of good manufacturing practices. FDA won't permit drugs to be made in substandard facilities. The FDA conducts about 3,500 inspections a year to ensure standards are met. Generic firms have facilities comparable to those of brand-name firms. In fact, brand-name firms are linked to an estimated 50 percent of generic drug production. They frequently make copies of their own or other brand name drugs, and sell them without the brand name.
(Source: FDA)

9. If brand-name drugs and generic drugs have the same active ingredients, why do they look different?

In the United States, trademark laws do not allow a generic drug to look exactly like the brand-name drug. However, a generic drug must duplicate the active ingredient. Shapes, colors, flavors and certain other inactive ingredients may be different.
(Source: FDA)

10. Are the non-active ingredients in generic medicines as good as those in brand name drugs?

Everything that goes into a medicine must be approved by the FDA, including the inert ingredients. Sometimes a generic manufacturer must change one or more of these because the brand company has patented the formulation of the specific drug. These changes in no way affect the effectiveness of the drug, since the generic manufacturer must show the FDA that the active ingredient still gets into your body to the same extent and rate as the brand name.
(Source: Generics Pharmaceutical Association)

11. Does every brand-name drug have a generic counterpart?

No. Brand-name drugs are generally given patent protection for 20 years from the date of submission of the patent. This provides protection for the innovator who laid out the initial costs (including research, development and marketing expenses) to develop the new drug. However, when the patent expires, other drug companies can introduce competitive generic versions, but only after they have been thoroughly tested by the manufacturer and approved by the FDA.

(Source: FDA)

12. What is the best source of information about generic drugs?

Contact your physician or pharmacist for information about generic drugs. You can also visit the FDA Web site at www.fda.gov for more information.

(Source: FDA)